Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world’s largest neurology specialty society representing more than 34,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer’s disease, Parkinson’s disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Lowering drug prices is a top priority for the AAN. We applaud the Center for Medicare and Medicaid Service’s (CMS) commitment to taking concrete steps to lower drug prices and increase access to care. The annual cost of treating neurologic disease in the United States exceeds $500 billion, and prescription drugs for neurologic conditions are some of the most expensive on the market. Medications prescribed by neurologists accounted for $5 billion in Medicare Part D payments in 2013, which trailed only internal medicine and family practice amongst specialties. High drug prices create unnecessary challenges for neurologists to deliver accessible and affordable care for their patients.

The Advance Notice of Proposed Rule Making (ANPRM) indicates that CMS will establish a pilot program under the Center for Medicare and Medicaid Innovation (CMMI), that would be mandatory for 50% of the country, targeting expenditures in the Medicare Part B program. While the AAN applauds CMS’s efforts to innovate and use market forces to lower drug prices, the AAN believes that instead of pursuing the current course, CMS should consider a different approach. Any true demonstration project should be voluntary, small scale, and centered on the quality and value of medical care provided to patients. This mandatory, wide reaching proposal

December 5, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
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Washington, DC 20201

RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs [CMS-5528-ANPRM]
does seem to not fit the typical definition of a pilot program. The AAN is concerned that this program lacks the evidentiary support that would be needed to justify such a wide launch. If CMS chooses to move forward with the model, the AAN recommends that CMS scale back the size of the program until the evidentiary basis is established showing that the proposal to index Part B drug prices against international reference prices will reduce Part B drug costs, without negatively impacting patient care. Additionally, the AAN believes that the proposal should account for the unique needs of Medicare beneficiaries through an open and deliberative process that involves all members of the affected communities including specialty societies and their patients.

The AAN also believes that the proposed program is not targeted correctly. Although the AAN does not believe neurologists choose medications in the course of treating patients because of potential financial gains, there are steps CMS can take to help limit perverse incentives and prevent unscrupulous prescribing from occurring. Such steps include helping societies like the AAN develop episodes of care that include the cost of medications to give the physician an incentive to reduce costs. Additionally, CMS should remove obstacles to forming APMs, especially those that will be considered qualifying APMs under the final Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) regulations. This further encourages physicians to choose medications for patient benefit, and not profit. By reducing obstacles, CMS will also minimize the adversarial, complex, and resource-consuming prior authorization process.

**Flawed assumptions**

The AAN fundamentally disagrees with CMS’ s thinking behind the International Pricing Index (IPI) proposal, which is based on the flawed assumption that physicians, including neurologists, practice medicine solely based on financial incentives rather than what is in the best interests of their patients. The foundational assumptions of this model run contrary to the idea that a physician’s preeminent concern is the wellbeing of his or her patients and assign blame for rising medication costs and utilization on physicians. This is a reasonable premise only for bad actors in the system and for the costs and medication usage that are related to decisions over which the physician has direct control. It is frequently the case, especially with single-source standard of care products, that physicians have minimal discretion over prescribing.

Ultimately, the primary driver of high drug costs is high list prices. High list prices are not under the control of individual physicians, but rather are set by pharmaceutical companies. The problem of exorbitantly high drug prices will never be resolved until manufacturers are held accountable for setting unaffordable prices. The AAN recommends that CMS ensure that policies aimed at lowering drug prices are targeted to the true drivers of high drug costs and are crafted with an understanding that a physician’s foremost concern is what is best for the patient.

**Impact on infusion centers**

The AAN is concerned this model as proposed will have a disproportionate and unreasonable impact on neurology practices with infusion centers. The pressure to provide affordable
access to biologics and other specialty medications has increased alongside the rising cost of care and declining reimbursement environment. If Part B reimbursement for these medications is further reduced, providers will no longer be able to sustain their infusion centers for Medicare patients and will have no choice but to refer them to their nearest available hospital, greatly increasing costs and further burdening hospital facilities.

Access to infusion services with oversight by a neurologist is essential for Medicare beneficiaries. Many of the complex drugs and biologicals that are administered intravenously for treatment of neurological conditions have the potential for severe allergic reactions, including anaphylaxis. The administration of many these infusions is not permitted in the home because of the need for medical monitoring and treatment. Additionally, many of the patients receiving these life-saving treatments are medically compromised, immune-suppressed, and neurologically impaired, requiring monitoring and/or intervention by the neurologist during the infusion. The in-office administration of certain infusions delivers value to the healthcare system by lowering patient and overall health system costs, while increasing patient access to high quality care.

The AAN believes CMS did not fully consider the impact this proposal will have on office-based infusion centers. For any proposed reimbursement model to produce positive effects on health outcomes, quality of life, and affordable access to care, treatment options must be both accessible and affordable for the patient, and financially sustainable for the provider.

**Need for greater transparency in drug pricing**

The lack of head-to-head comparisons of medications makes it difficult for neurologists to determine which particular treatment is truly the most cost-effective. The AAN agrees that neurologists need to be cost-conscious in terms of the medications they prescribe, but not at the expense of a patient’s health. Neurologists lack a transparent pricing system to guide the prescribing of medication. For example, unless a neurologist calls several pharmacies themselves to inquire on each patient’s prescription, they will have no idea as to the total cost to payers and patients. The proposal puts the burden of the high cost of medications on patients and the responsibility on physicians who lack the data to judge comparative effectiveness of different treatments. The proposal does not address the underlying issue that neither the marketplace nor regulations have put any cap on medication costs. If neurologists have more information at their disposal, they can help bring down costs without risking the unintended consequences that will occur because of this proposal.

**Issues associated with a lack of vendor competition**

The AAN is deeply concerned by the proposal to implement the program as a mandatory program in 50% of the country without a guarantee of sufficient vendor participation. The proposed model will be subject to many of the same issues as the previous iteration of the Competitive Acquisition Program (CAP) if there isn’t robust competition between vendors for physician participation.

Prior to implementation, CMS should ensure that there will be a sufficient number of vendors in all areas of the country so that patients and providers have unrestricted access to
lifesaving drugs. The AAN is deeply concerned that individual vendors have a financial incentive to cease providing certain drugs to physicians, if drug manufacturers are unwilling to offer low enough prices to make the model’s indexed reimbursement worthwhile for the vendor. The AAN thinks it is highly likely that there will be situations in which vendors cannot acquire single-source drugs at the vendor’s desired price level, as there is minimal incentive for monopolistic manufacturers to discount their products, due to a lack of competition. According to HHS the proposed IPI model will be implemented “without any restrictions on patient access.” The AAN requests clarification on how the model will address situations in which vendors are unwilling or unable to purchase and distribute lifesaving drugs covered by the model to participating providers due to a breakdown in negotiations with manufacturers. Currently, Part B provides coverage for whatever is “reasonable and necessary for the diagnosis or treatment of illness or injury.” Will vendors be required to meet that standard? If not, will model participants be able to acquire Part B products through the existing buy-and-bill system if no vendor is willing to provide a needed product? Assuming there is vendor competition, will model participants be able to immediately exit agreements if a vendor refuses to provide a medically necessary Part B product?

The AAN is also particularly worried that there will not be sufficient vendor competition in the IPI model to ensure that participating physicians are protected from paying extremely high fees as a condition of participation. In the ANPRM, CMS states that the agency “envision(s) that model vendors would compete, in part, for physicians and hospitals based on low fees.” CMS anticipated that there would be a robust competitive bidding process under the original iteration of the CAP. Robust competition never materialized and participating physicians were stuck with just a single approved vendor. The AAN is concerned, in the event that history repeats itself and there isn’t robust vendor competition, that physicians forced into this mandatory model will have no recourse against a monopolistic vendor extracting extremely high fees from providers. If CMS proceeds with implementation of the proposed model, guardrails need to be in place to ensure that fees are capped, and providers are protected from predatory behavior on the part of a monopolistic vendor.

Furthermore, the AAN believes that the program will create a significant burden on physicians if physicians have no recourse or ability to switch between vendors if a particular vendor places significant burdens on their practice. During the previous iteration of the CAP program, many physicians reported wanting to exit their contracts with the sole CAP vendor but did not have any ability to do so until the full-year contract term elapsed. Many physicians reported frustration with excessive paperwork requirements and the high volume of phone calls and other communications that were needed when acquiring drugs from the

2 CMS-5528-ANPRM, p. 21-22
sole participating vendor. If participating physicians are not allowed to exit the program or switch between vendors, due to a lack of options and mandated participation, then they will have no choice but to comply with any overly burdensome requirements imposed by the vendor.

The AAN is also concerned with the idea of middlemen being inserted into the process of acquiring Part B drugs. The AAN believes that vendors, regardless of market competition, will increase transaction costs associated with purchasing and administering Part B drugs. Even if the model achieves desired savings for the program overall, these savings will at least be partially offset by increased costs imposed on providers participating in the program in the form of vendor fees.

Additionally, to ensure patients have access to needed medications, CMS should require that vendors provide same-day shipping, so providers can administer necessary drugs to patients at the time of the patient’s visit. Under the CAP, some patients reported an increase in return visits for drug administrations. This was because the singular CAP vendor did not offer same day shipping of drugs, which meant that participating physicians could not administer prescribed medication on the same day as a patient’s visit with the provider. This created significant administrative burden and access to care issues for patients and providers and was especially problematic for patients in rural settings who were subject to long travel times for return visits.

**Part B drug spending is not a major problem**

The AAN is concerned that this proposal is not properly targeted to address the actual driver of high drug costs. CMS has expressed concern that the 6 percent Average Sales Price (ASP) add-on payment may encourage the use of more expensive products because the add-on to the medication’s cost is a percentage of the sales price. However, this assumption does not take into account the fact that providers’ prescribing decisions depend on a variety of factors including the clinical characteristics and complexities of the patient population. Additionally, the AAN is aware of no evidence indicating that the payment changes contemplated by the model will improve quality of care. Contrary to CMS’s stated goal, the AAN is concerned that this proposal may adversely impact patients.

Additionally, data suggests that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment. It is important to note that Part B expenditures have been relatively stable, remaining lower than the overall rate of medical inflation over the past 5 years, and Part B medications account for just 3 percent of total program costs.

**Proposed IPI model is likely to be ineffective due to gaming**

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In June, Secretary Azar testified before the Senate Health Committee and in stark contrast to the proposal, indicated opposition to a program that would set reference prices for drugs based on the prices paid by peer countries. The Secretary indicated that pharmaceutical companies could easily devise strategies in foreign markets that would actually result in Americans paying more for drugs. This sentiment was echoed in the administration’s drug pricing blueprint. The AAN is surprised and concerned by the policy reversal inherent in the IPI and believes that the Secretary’s June reasoning was sound.

The pharmaceutical industry is likely to employ creative strategies in foreign markets to protect profits. It is possible that drug companies could pull their drugs from foreign markets with low reference prices so as to drive up the price paid in the United States. Additionally, to circumvent the reference price set in the IPI, drug companies could work with foreign governments to set artificially high list prices that would be incorporated in the IPI index, and then offer substantial rebates to foreign entities, so that they can continue to effectively pay artificially low prices. The AAN is very concerned that the proposed model is rife with potential opportunities for abuse, which could reduce patient access and increase the prices paid for lifesaving Part B drugs. Any foreign input used to determine an index price could potentially be gamed by a pharmaceutical manufacturer with a strong profit incentive to do so. The AAN recommends that prior to implementation, guardrails need to be implemented and tested to deter potential model gaming.

**Opposition to allowing vendors to implement indication-based pricing**

In the ANPRM, CMS asks if model vendors should be allowed to enter into value-based payment arrangements including indication-based pricing. The AAN opposes allowing vendors to implement indication-based pricing. Indication-based reimbursement to providers has the potential to limit patient access to necessary drugs, create financial disincentives for physicians to provide the most appropriate treatment, and adversely affect the clinical management of patients. Defining a pharmacy benefit based on diagnosis may harm some patients in a diagnostic category in which a medication is known to have some benefit, but the effect is understudied. This is particularly common in neurology where drugs in various categories (e.g., anticonvulsants, antipsychotics, and antidepressants) are often prescribed for off-label use to treat a condition not supported by an FDA on-label indication. To ensure patients can access critical Part B therapies, physicians must be able to cover the costs associated with the purchase, storage, maintenance, replenishment, and handling of the medications. Cuts to the reimbursement rate for Part B drugs for certain indications could disadvantage physicians who furnish those medications for off-label use. In these situations, payment rates for some indications may be lower than acquisition costs.

If physicians are unable to offer Part B drugs due to indication-based payment rates, patients will suffer. Some patients may need to seek treatment in higher cost sites of service like hospital outpatient departments while physicians may be forced to prescribe suboptimal

9 “Testimony before the Senate Health Committee on President Trump’s Plan to Reduce Prescription Drug Costs for Patients.” Secretary of Health and Human Services Alex Azar, June 2018.
11 CMS-5528-ANPRM, p. 25
medications because the most appropriate option is not reimbursed. Indication-based payments create disparities for physicians and their patients as expensive therapies will only remain available in practices capable of absorbing the difference between the high acquisition costs and low reimbursement rates.

Under an alternative indication-based payment policy structure, CMS may be able to mitigate some of these issues by ensuring that each indication for a product is assigned its own Healthcare Common Procedure Coding System (HCPCS) code and its own Average Sales Price (ASP)-based payment amount. If each indication has its own ASP and code, payments for individual indications may better correspond to the acquisition cost.

Unless CMS can administer an indication-based payment policy that adequately accounts for acquisition costs, the AAN strongly opposes any Medicare Part B drug payment policy that creates significant financial disincentives to prescribe optimal treatment.

**Conclusion**

Reducing exorbitantly high drug prices is a top priority for the AAN. We appreciate CMS’s commitment to reducing extremely high drug costs that negatively impact patients and providers across the country. The AAN believes that the international pricing index model, as currently proposed, has the significant potential to compromise patient access to life-saving Part B drugs and impose significant burdens on providers. The AAN asks that CMS reconsider this proposal and work with patient and provider groups to formulate a proposal that would address the true drivers of ultra-high drug costs, without compromising patient care.

Thank you for the opportunity to provide comments on the proposed international pricing index model. Please contact Daniel Spirn, Senior Regulatory Counsel at dspirn@aan.com or Matt Kerschner, Government Relations Manager, at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

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